A STUDY ON PALLIATION OF CARCINOMA OF OESOPHAGUS WITH SELF EXPANDABLE METAL STENT

DISSERTATION SUBMITTED FOR

DM - MEDICAL GASTROENTEROLOGY (BRANCH-IV)

FEBRUARY-2006.

THE TAMIL NADU

DR. MGR MEDICAL UNIVERSITY,

CHENNAI, TAMIL NADU.

CERTIFICATE

This is to certify that this dissertation entitled " PALLIATION OF CARCINOMA OF OESOPHAGUS WITH SELF EXPANDABLE METAL STENT" submitted by Dr. Karthikeyan. R, to the Faculty of Medical Gastroenterology, the Tamil Nadu Dr. MGR Medical University, Guindy, Chennai-600 032, in partial fulfillment of the requirement for the award of DM., Degree Branch IV (Medical Gastroenterology) is a bonafide work carried out by him under my direct supervision and guidance.

Prof. S. Jeevan Kumar, MD., DM.,

Professor & Head of The Department,
Department of Digestive Health & Diseases,
Government Peripheral Hospital, Anna Nagar,
Attached To Kilpauk Medical College,
Chennai - 600 010.

ACKNOWLEDGEMENT

At the outset I wish to express my thanks to our Dean Dr.G.Ilangovan, MD., DD., DIH., Ph. D., Government Kilpauk Medical College, Kilpauk, Chennai- 600 010 and Dr.M. Anand Babu, MS., Civil Surgeon Medical Officer, Government Peripheral Hospital, Anna Nagar, Chennai- 600102, for permitting me to utilize the clinical materials from this hospital.

I wish to express my sincere thanks and gratitude to my Professor, Dr. S. Jeevan Kumar, MD., DM., Head of the Department, Department of Digestive Health & Diseases, Government Peripheral Hospital, Anna Nagar, attached to Kilpauk Medical College, Chennai- 600 010, for his meticulous guidance and constant encouragement throughout the study.

I am extremely thankful to our Former Professors Dr. S.Subash, MD., DM., & Dr. S. Rajani Kanth., MD., DM. for their able guidance.

I am extremely thankful to our beloved Senior Faculty Members Dr. Mohammed Ali., MD., DM., Dr. P. Padmanabhan., MD., DM., and Dr. A.R. Venkateswaran., MD., DM., for their help and eminent guidance through out the study.

I am thankful to all the faculties of the Departments in Government Peripheral Hospital in general and Radiology Department in particular for their kind co-operation throughout the study.

I extend my thanks to Chief Minister and Health Minister of Tamil Nadu and

Government of Tamil Nadu for financial assistance to purchase the expensive metal stents and providing infrastructure to the department to serve and provide the State of Art treatment facilities to the poor patients.

It is a special pleasure to acknowledge the help of staff nurses and endoscopy assistants Mr. Palani & Mrs. Rajeshwari for their deep commitments to the work.

I owe special thanks to my post-graduate colleagues Dr. C.Krishnan, Dr. M. Kannan, Dr. M.Geetha, Dr.R.Balamurali, Dr. S.Thamarai Selvan, Dr. P. Nageswara Rao and Dr. G. Balasubramanian for their support and encouragement.

I thank all the referring Institutions and doctors for their trust and timely referral of needy patients to our department.

I thank all the patients who have ungrudgingly lent themselves to undergo this study without whom this study would not have seen the light of the day.

TABLE OF CONTENTS

INTRODUCTION

Carcinoma of oesophagus is one of the most debilitating disease that deprives a person from the joy of eating food. It frustrates the patient because of the mechanical effect resulting in dysphagia and infiltration to the nearby structures resulting in excruciating pain. When the tumour extends into respiratory tract further worsens the nutritional status by aggravating the dysphagia cough and aspiration on swallowing and associated respiratory infection and negative nitrogen balance add to the problem. At the time of presentation of symptoms most of the patients are in advanced malignancy. Unfortunately this disease is increasing in our country due to the changing trends in people's lifestyle and food habits.

The most distressing symptom for the vast majority of patients with malignant obstruction of the oesophagus is dysphagia. The relief of this condition associated with nutritional and psychosocial support must be the primary goal of palliation. More than 70% of patients with neoplastic disease of the oesophagus or oesophagogastric junction at the time of diagnosis are not suitable for curative surgical resection (1) because of advanced local disease, extensive distant metastases, or both. Therefore, these patients are palliatively treated, either by surgery, radiotherapy, chemotherapy or endoscopic therapy.

At the present time, approximately 10% of patients with oesophageal cancer survive five years. Thus, approximately 90% are incurable and will need some form of palliation. The morbidity of radiation and chemotherapy can be managed well by alterations of dosage and frequency. In selected patients with distal lesions, surgical therapy may offer good palliation of dysphagia at the price of operative risk and postresection sequelae.

The **optimum palliative care** for the majority of patients with oesophageal cancer should include the safest, most effective, and least expensive therapies that can be performed promptly as the

need arises. All too often, quality of life is neither protected nor supported adequately between the stage of recognized incurability and death.

The overall five-year "cure" rates for these neoplasms (5) have not changed, despite the excellent progress made in supportive care, surgical technique, radiation, and chemotherapy except in highly selected patients. The reason for the persistently poor results is that oesophageal cancer is rarely diagnosed early enough to do curative treatment.

General supportive care, relief of pain, restoration of adequate nutritional status, and treatment of specific sequelae of the carcinoma are all essential to proper therapy. No single method is adequate for palliating oesophageal carcinoma, especially dysphagia.

LITERATURE REVIEW ON

PALLIATION OF CARCINOMA OESOPHAGUS

Dysphagia literally means difficulty with eating, but the term is used clinically to indicate difficulty in passage of solid and liquid boluses through the oesophagus to the stomach. The presence of dysphagia as a presenting symptom of oesophageal cancer usually is indicative of incurability.

The normal oesophageal lumen measures approximately 25 mm in functional diameter. When the lumen diameter is decreased to 13 mm, everyone has solid food or regular diet dysphagia (2). When the lumen diameter is less than 18 mm, selective alteration of diet content (17) and consistency is necessary, depending on the characteristics of the stricture.

The average patient with carcinoma oesophagus has had significant, easily recognizable dysphagia for at least three to six months before seeking medical care. Obstructive dysphagia correlates with more than 50% occlusion (16) of the oesophageal lumen and usually indicates extensive intramural spread of the cancer. Most patients also have 5 cm (13) or more of longitudinal intramural oesophageal involvement at diagnosis. Sialorrhea or excessive saliva production is regularly associated with oesophageal obstruction that contributes to frequent spitting in daytime, as well as insomnia and the increased risk of aspiration pneumonia. The presence of chest pain at initial presentation is also a poor prognostic sign.

Lumen restoration techniques performed with the aid of endoscopy are reviewed. The nonsurgical treatment methods discussed are applicable to those who have had prior attempts at curative and palliative therapy, as well as to those rare patients who elect to have no formal initial therapy for the obstructing lesion.

The commonly used palliative therapies for Ca. oesophagus (14, 15) are:-

1. Endoscopic Dilatation - Wire guided poly vinyl bougies & wire guided and non wire guided balloon

dilators

2. Laser Ablation

3. Thermal Ablation- BICAP Tumour probe, Argon plasma coagulation.

4. Chemical Ablation- Chemotherapeutic Agents & sclerosants

5. Oesophageal stent- Plastic & Self Expandable Metal Stents

6. Systemic Chemotherapy

7. External Beam Radiotherapy & Brachytherapy

8. Newer Modality- Photo Dynamic Therapy, Endoscopic Mucosal Resection.

9. Pain therapy & Nutrition care.

ENDOSCOPIC DILATATION

The first order of therapeutic protocol should be to care for the patient's nutrition, pain, and psychological needs. Also, the stenotic oesophageal lumen needs to be restored to a diameter sufficient to allow ingestion of liquids and some solid food as well to improve clearing the significant volume of saliva produced every day. Peroral dilation should begin as soon as possible in patients with dysphagia. Though there is a fear of increased risk of perforation in dilating the post radiation stricture, when proper instruments and techniques are used, risk in dilating a malignant stricture before, during or after radiation therapy is minimal.

In many cases, patients present with obviously incurable and obstructing lesions but are not referred for early dilation either before chemotherapy and radiation therapy are begun or after those treatments have failed to provide dysphagia relief. This hesitation causes the patient needless suffering for many weeks. Although the improved lumen patency provided by timely dilation is limited, even temporary relief with improved swallowing is beneficial.

Within three to six weeks after palliative chemoradiation therapy, the optimum lumen restoring response can be expected. Dysphagia may recur due to recurrent tumor, radiation-induced stricture (12), or both. In any of these instances, dysphagia palliation with dilatation promptly recommended.

Milder degrees of stricture are easier and safer to dilate than severe strictures (11). It is illogical to delay therapy until the patient is able to swallow only liquids, even though adequate total caloric intake has been possible by using a full liquid diet plus dietary supplements.

Peroral dilation can restore oesophageal lumen patency, albeit temporarily, to a diameter adequate to permit adequate swallowing in over 90% of patients. Either flexible, tapered dilators (Savary) (10) passed over a guide wire or rubber dilators (Maloney) are used in progressive sizes under fluoroscopic control. Balloon dilators either TTS (Through The Scope) Balloons or wire guided balloons are used. Balloon dilators use a radial force to dilate the stricture, where as polyvinyl dilators use axial shearing force to dilate the lesion, thus there is more chance of complications with the latter dilators (12).

Most malignant strictures can be safely dilated in several sessions to a size 48F to 51F (16 to 17 mm) (15). Lumen diameter must be greater than 39F (13 mm) (11) if solid-food dysphagia is to be at least partially relieved. A maintenance program for frequency of dilation is an individual matter based on each stricture's response. Although adequate lumen diameter can be restored by dilation, recurrent lumen stenosis occurs within days to a few weeks so any relief obtained usually is of short duration. When a short-term response is observed, the therapist needs to start planning and educating the patient about the next options for more prolonged palliation.

There is no evidence that properly performed oesophageal dilation of obstructing carcinoma carries an unacceptable risk. Various studies reported a 80-92% success rate (11,12,14,15) for dilation. Minor complications (14) are chest pain, odynophagia, fever, bacteremia, minor bleed, nontransmural mucosal tear, broncho spasm & asymptomatic cardiac arrhythmia (12) and major complications are

perforation (1%-4%), oesophageal hematoma (<1%), new fistulas, major bleed, pneumothorax, pleural effusion and rarely procedure related death (0.01%-1%) (53).

Advantages of the dilation include simplicity, low cost, wide availability, short procedure time and relative safety. Pitfalls of the dilation are short lived relief, pain during procedure, as disease progresses symptom free interval shortens. So dilation alone is inadequate for satisfactory palliation in most patients.

THERMAL LUMINAL RESTORATION THERAPY

THERMAL LASER ABLATION

Transendoscopic ablation of obstructing intraluminal cancer by laser thermal coagulation offers another relatively safe but often temporary palliation for dysphagia. Laser ablation is most helpful for treating lesions that are polypoid or that occlude by intraluminal growth. Laser therapy carries a higher risk and is less effective for cancer of the proximal oesophagus or oesophagogastric junction, tortuous lesions, lesion more than 5cms, very tight and hard lesions, subepithelial metastasis in a diffuse pattern, excessively angulated lesions, and presence of an oesophagorespiratory fistula.

Transendoscopic laser ablation of obstructing oesophageal cancers was first described in 1982 using high-power Neodymium Yttrium-Aluminum-Garnet (Nd:YAG) laser(19). The degree of dysphagia relief is less predictable after laser therapy. Successful ablation usually provides a wider lumen diameter and allows intake of a more solid consistency diet temporarily. The maximum benefit is observed a few days after treatment, but dysphagia gradually recurs and requires repeat therapy sessions, usually every four to six weeks for life.

One helpful application of laser ablation is for pre-stent ablation (20) of a polypoid, eccentric intraluminal mass. Other special cases in which laser may help include hemostasis for necrotic chronic

bleeding lesions and for ablation of tumors obstructing a stent by overgrowth at either end or by ingrowth through an uncoated metal expandable stent.

Laser can be used as contact (low power setting) or non-contact (high power setting) method. Laser used in a power setting of 40-100 W (21) in one second pulsed or continuous mode. Combination of vaporization and coagulation necrosis occurs during laser application. Due to the edema sometime initially dysphagia worsens (22). Ideally, the laser ablation should begin at the distal margin of a circumferential lesion after dilatation to allow safe aiming of the laser beam. The ablation is then continued as the endoscope is slowly retracted 1 cm intervals. When complete luminal occlusion is present, antegrade (23) laser application is used. Laser ideally delivered with double channel endoscopes to reduce the gaseous distension and to clear the field. Patients are routinely evaluated 48 hrs- 1 week later and retreated until maximal luminal patency is achieved.

Although the technical success (ability to relieve the oesophageal obstruction) is approximately 90- 97%, the functional success (the ability to maintain adequate nutrition by peroral intake) is only approximately 70- 85% (21, 24). Overall complication rate is 4.1% including 2% chance of perforation, but these can be reduced with proper case selection.

Luminal patency in carcinoma oesophagus does not equate with improvement in dysphagia. Adequate nutrition is hindered to varying degrees because of tumour infiltration, radiation- or laser-induced neuromuscular injury or fibrosis, and by the anorexia related to cancer. Mean survival time following thermal laser ablation is similar to other ablation methods there is no survival difference.

CONTACT THERMAL THERAPY

Electrosurgical tumour probe therapy uses mainly BICAP- tumour probe which has circumferential plates (360 degree) around the olive cylinder. It is passed over a guide wire. Depth of coagulation necrosis varies with power settings and the duration of application. The procedure

performed under fluoroscopic and endoscopic control. With BICAP tumour ablation done with Power setting of 50 w - 15 seconds- per each station (18). It is recommended to do retrograde approach. In which the probe is pulled back over a guide wire in 1 cm interval. Active electrode is 1.5cm in length so some overlap occurs in the tissue injury.

Short segments may be treated with antegrade fashion under endoscopic guidance. In follow-up endoscopy (18) 48 hrs later necrotic derbies are removed and additional therapy applied on the basis of results. Technical success (18) and improvement in dysphagia reported in 80-90% of patients. Mean duration of palliation of 7.6 weeks.

BICAP tumour probe is best suited for bulky or infiltrating symmetrical circumferential tumours. It is ill suited for asymmetrical lesions, tortuous segments and tight stenotic tumours. Advantages are its low cost and ability to treat large extent of tumours in a single sitting. In advertent treatment of opposing or marginal non malignant tissue may result in pain and stricture.

ARGON PLASMA COAGULATION

Argon plasma coagulation delivers monopolar electrocoagulation by using a stream of ionized Argon gas ignited by a high voltage discharged at the tip of a catheter probe. Application and control are easier. Depth of treatment is uniform and consistent although it is superficial. Problem with the depth of injury is too shallow so that it is insufficient to effect relief of dysphagia associated with oesophageal carcinoma (16).

CHEMICAL ABLATION

Intraluminal tumor mass can be reduced by direct transendoscopic injection of absolute alcohol (25) and other sclerosing agents like polidocanol, sodium morrhuate or chemotherapeutic agents (27). Mechanism of tumour destruction is chemical necrolysis (25). Hemostasis achieved with local edema,

vasoconstriction and thrombosis. These methods offer inexpensive and safe alternatives to therapy by other ablative methods; however, clinical experience is limited, and long-term follow-up is lacking.

Transendoscopic injection of absolute alcohol, using a standard sclerotherapy needle, has been reported as safe, simple, and effective. Initial results are similar to laser therapy. The injected tumor necroses and sloughs within several days after absolute alcohol injection. Repeat sessions are needed. In the small number of cases reported thus far, complications have been rare, and costs above the basic endoscopy charge are minimal. Alcohol injection is contraindicated in patients with infiltrating or minimally protruding tumors due to the risk for perforation. Disadvantages of the procedure are inability control the depth of tissue injury and the lack of immediately visible tissue effects.

PHOTODYNAMIC THERAPY

Photodynamic therapy (PDT) begins with administration of a chemical photosensitizer that accumulates in higher concentrations in neoplastic tissue than in normal tissue. This chemical, porfimer sodium is given intravenously in a dose of 2 mg/kg of body weight (26,28,29). After approximately 48 hours, the area of cancer is exposed to a red light with a wavelength of 630 nm provided by a continuous-wave argon-pumped dye laser via a quartz fiber passed through a standard videoendoscope. This light exposure initiates a chemical reaction of the porphyrin compound within the cells that leads to production of oxygen radicals that destroy the cells. After another 48 hours, residual tumor can be similarly treated since an adequate concentration of the photosensitizer remains. Patients remain photosensitive to sunlight for one to two months and must avoid such exposure. Transient side effects include odynophagia, chest pain, low-grade fever and, uncommonly, minor pleural effusion. There is a 1% perforation rate reported in the largest series to date (30).

The overall efficacy of PDT compared to Nd:YAG laser (31) is comparable. PDT is considered to be technically easier, less operator dependent, and less painful than laser in patients under conscious

sedation. The time to palliation failure of one month was comparable for PDT and thermal laser therapy. The cost of PDT is high due to the cost of porfimer sodium plus multiple endoscopies and hospital observation to manage the possible short-term side effects. PDT has also been used recently to treat tumor ingrowth (29,31) in expandable oesophageal stents.

An emerging indication for Photo Dynamic Therapy is tumour down staging (30). After PDT some of the initially unresectable tumours became resectable. RCTs are going on in this direction till then it is very costly tool for palliation of carcinoma of oesophagus.

OESOPHAGEAL STENTS

EARLY PHASE:

Little did CHARLES STENT know that his development in 1856 of a thermoplastic material (33,34) for dental impressions would set in motion the development of one of the fastest growing medical device technology. Other early pioneers in that field were Leroy d'Etoilles used ivory and Sir Charter Symonds (35) used boxwood tubes for palliation of malignant dysphagia.

Palliation of dysphagia due to oesophageal cancer by placement of peroral stents has been performed for over 100 years but was not safe and effective until the 1950s. Stents or prostheses have been made from animal tusks, coiled silver wire, raw gum latex, rubber, polyethylene, polyvinyl chloride, and silicone; more recently, either stainless steel wire and space age alloys or memory metals have been used to construct metal stents that are expandable.

NITINOL:

The discovery of Nitinol (Nickel & titanium alloy) developed by US Navy revolutionized the palliative endoprosthesis development (55). Super elastic Nitinol used mainly since it is biocompatible, kink resistant, self expandable, fatigue resistant and adverse to dynamic interference. So it will have good expansion after deployment, maintain the shape and does not migrate despite peristaltic activity.

RADIAL EXPANSION AND RADIAL COMPRESSION FORCE:

Radial expansion force is the one that makes the stent to expand outward from its center and resist compression. It is developed from the geometric design (55) of the stent and the property of the stent material. The Radial compression force is the force exerted by the luminal wall to compress/collapse the stent. So, Radial expansion force must be higher than Radial compression force to keep the stent in an expanded state.

FORESHORTENING:

Defined as the 'percentage of difference between the constrained length of stent and deployed length of stent'. Smaller lumen stents have less foreshortening (56). It also depends on the stent design. Stents with interlocking knot design have less foreshortening than braided or movable designs.

TISSUE RESPONSE TO SELF EXPANDABLE METAL STENT:

Human studies after Self Expandable Metal Stent deployment shown an early changes (58) (<1 month after stenting) in the form of superficial necrosis of mucosa/ tumour due to the pressure from the expanding the stent that migrate into the submucous space. Coated stents do not migrate, but their bare funnel portions do. Late changes (58) (>1 month after stenting) stent covered by a layer of collagen/ fibrous tissue and epithelialization occurs. Again it will not occur in the covered stents but their uncovered funnel portion develops these changes. The advantage of this phenomenon is low rate of stent migration (36), the disadvantage is lumen compromise, tumour ingrowth and stent became unremovable after stenting.

IDEAL STENT:

The ideal stent (37) should be simple to insert, fix and remove: painless, long lasting, safe, biocompatible, incompressible, somewhat flexible, thin walled, have a large lumen, be able to accommodate varying oesophageal dimensions, be inexpensive and require only brief hospitalization.

The stents available in the market belong to broad categories. One is Plastic stent another group is Self Expandable Stent including both Metal and plastic stent. A brief summary about the property of

these two groups of stents and comparison between and among them is given below.

PLASTIC STENTS:

Non expandable plastic tubes are made from latex, silicone or plastic material. Proximal flange/ funnel portion to seat at the proximal margin of the growth. Addition of nylon, plastic or metal coils to the shaft of a prosthetic device also aids in anchoring and reduces displacement.

Names of the plastic stent (39) available: 1) Tygon Tube (Tytgat), 2) Wilson-Cook stent, 3) Atkinson stent 4) Medoc- Celestin Tube, 5) Eska- Buess oesophageal tube, 6) Wilson-Cook Fistula prosthesis, 7) Eska- Buess Fistula funnel.

SELF EXPANDABLE STENT:

Self Expandable Metal Stent are made of Stainless steel (Z- stent), Elgiloy (Wallstent), Nitinol (Choo, Ultraflex, Esophacoil & Do stent)

SELF EXPANDABLE STENTS:

1) Wallstent (I- Dog bone type, II- Flare type and newer Flamingo type) from Boston Scientific/Microvasive, Natick, Massachusetts.
2) Z – Stent (Type- A, B, C, D, E, F, Gianturco- Rosch variant & Song Variant) from Wilson-Cook, Winston-Salem, North Carolina.
3) Ultraflex stent (covered and uncovered) from Boston Scientific/Microvasive, Natick, Massachusetts.
4) Choo Stent (covered and uncovered) from M.I. Tech Co.
5) Do Stent with Anti Reflux Valve from M.I. Tech Co.
6) Esophacoil from Medtronic/Instent, Eden Prairie, Minnesota.
7) Polyflex Stent made of polyester wire mesh- Self Expanding Plastic Stent.

COMPARISON BETWEEN METALLIC STENT & PLASTIC STENT

NO	PARAMETER	METALLIC STENT	PLASTIC STENT
1	DYNAMIC EXPANSION	YES	NO
2	RADIAL FORCE	YES	NO
3	FLEXIBILITY	YES	NO
4	HIGH INTERNAL AND EXTERNAL SIZE RATIO	YES	NO
5	BIO REACTIVITY	MORE	LESS
6	REMOVABLE	NO WHEN INCORPORATED	YES
7	RISK OF MIGRATION	LESS	MORE
8	MOLDING TO VARIOUS FIRMNESS	NO	YES
9	FORESHORTENING	YES EXCEPT- Z-STENT	NO
10	SHAPE MEMORY	YES	NO
11	POSITION ADJUSTMENT	NO EXCEPT CHOO, DO. SONG STENTS	YES
12	OESOPHAGEAL PERFORATION	LESS	MORE
13	DEFORMATION	CAN OCCUR	NO
14	COST	MORE	LESS
15	MARMEN EFFECT*	NITINOL STENTS	NO

*** Marmen effect (55)**- characteristic feature of the Nitinol Stent, it denotes change of shape in response to temperature. There is distortion of the alloy at low temperature (martensitic effect), and then reverting to their original shape when reheated (Austenitic effect). Insertion of the stent is achieved in the martensitic effect and stent inside body expands by austenitic effect (from body temperature).

COMPARISON AMONG SELF EXPANDABLE METAL STENTS

NO	PARAMETER	SELF EXPANDABLE METAL STENTS					
		W	Z	U	E	C	D
1	Compressibility	+	+	+	+	+	+
2	Flexibility	+	+	+	+	+	+
3	Rigidity	--	--	--	--	--	--
4	Large lumen	--	+	+	+	+	+
5	Thin wall	+	+	+	+	+	+
6	Quality of eating	G	G	G	G	G	G
7	Tissue infiltration	+	+	+	+	N	N
8	Risk of migration	Y	Y	Y	N	N	N

9	Removability		N	N	Y	Y	Y	Y
10	Reflux & aspiration		Y	Y	Y	Y	Y	N
11	Post intubation complications		Y	Y	Y	N	N	N
12	Appropriateness in difficulty stenosis							
12	a)	Across OG junction	N (except flamingo)	N	N	N	N	Y
12	b)	Proximal bulky tumour	N	N	Y	N	Y	Y
12	c)	Angulated lesion	N	N	Y	Y	Y	Y
12	d)	Multiple strictures	N	N	Y	Y	Y	Y
12	e)	Extrinsic obstruction	N*	N*	N	Y	Y	Y
12	f)	Fistula	N*	N*	Y	Y	Y	Y

W- Wallstent Z- Z Stent U- Ultraflex Stent

E- Esophacoil C- Choo Stent D- Do Stent

- = No + = Yes G = Good Y= Yes N= No

* = this problem is not present in the Covered modification of this stent

PREPROCEDURE DILATATION:

Thermal ablation by Nd:YAG laser, multipolar electrocoagulation probe or heater probe, chemical ablation, argon plasma coagulation are used for pre-stent lumen preparation. It is necessary to plan adequate dilation over several sessions before plastic stent placement but in the SEMS overzealous dilatation may increase the chance of migration (32).

DIAMETER OF THE STENT:

The diameter of stent-related lumen restoration varies between 9 and 25 mm (36,37). Plastic and silicone stents have lumen sizes of 9 to 12 mm (41). Metal expandable stents are advertised to have potential lumen diameters up to 25 mm (43); however, the maximum advertised diameter is not

predictably achieved because stricture resistance often exceeds stent radial force. Metal stents with high radial expansile force can achieve larger diameters but at a higher risk of perforation and greater difficulty with rapid extraction when emergent removal is indicated.

STENT POSITIONING:

The concept for proper stent location requires that the stent extend atleast 2.5 cm above and below the obstructing lesion (42). For metal stents that are uncoated at each end, the 2.5-cm overlap measurement should be calculated to allow 2.5 cm of coated stent above and below the lesion if possible. Positioning the stent in this fashion helps to compensate for the possibility of the carcinoma to overgrow either end or to grow through the uncoated wire mesh at either end and obstruct the lumen. This degree of extension beyond the lesion usually is adequate to prevent overgrowth of the cancer.

PROCEDURAL MORBIDITY:

Stent placement is done under conscious sedation.

When proper technique is used, the perforation risk for peroral oesophageal stents will be less than 5% and the mortality near zero (41). In a recent series of plastic stents, the perforation rate was 2.8% and stent-related mortality was 1.8% (42). In patients having metal expandable stents, there were no perforations. The high mortality and perforation rate for plastic stent is believed to be due to the lack of programmed pre-stent dilation and to the type of stent and introduction apparatus used. A recent report says that chemotherapy does not increase the risk of complications with metal stents. Usually, only one or two days of hospital observation is necessary unless the patient is suffering from other problems associated with advanced disease. In 90% of patients, the stent remains in position for life (36) and usually permits adequate swallowing of liquids and a modified soft diet.

DIFFICULT AREAS:

As with other palliative therapies, increased risk and technical difficulty are concerns for lesions in the cervical oesophagus (68,69,70) and at the gastroesophageal junction(45). In cervical oesophagus

cancer stents are safe and effective in approximately two thirds of patients. Lesions of the lower oesophageal and gastric cardia can be effectively stented.

Rarely, stent placement can precipitate airway obstruction in the upper oesophagus. This will more likely occur if airway compromise by tumor involvement already exists. All patients having a stent placed for an oesophageal cancer cephalad to the level of the left main bronchus should have pre-stent bronchoscopy to exclude existing airway compromise by the carcinoma.

POST PROCEDURE:

Once some metal stents are placed, they cannot be easily repositioned and are either very difficult or impossible to remove. Plastic and metal stents become dislocated in 5% to 10% of cases but usually can be properly repositioned (44,46).

Food impaction is usually due to a lack of patient education or noncompliance with instructions for proper food selection, chewing, and swallowing. Stent diet instructions, verbal and written, should be given to patients and family members or caregivers prior to patients' discharge from the hospital.

POST STENT SURVIVAL:

The timing for placement of either plastic or metal expandable stents is important for procedure safety, quality of life, and duration of survival. This short survival (35,53) is in some measure due to the habit of late referral. Unfortunately, physicians in past years have neglected to refer patients for stents until very late in their illness. Nearly all series report the average survival after stent placement to range between three and five months (5, 53).

Overall survival has not been improved by metal stents compared to plastic stents (53, 41,43). But the stent deployment related complications are higher in plastic stents, relief of dysphagia is also inferior to Self Expandable Metal Stent group and post procedure hospital admission are higher in plastic stent group. The unacceptable complication and mortality rates associated with plastic and silicone oesophageal stents (41,43) occurred after development of commercial insertion devices that were larger and more rigid than necessary. The other major negative factor in plastic stent safety was

the practice of single sitting dilation & stent deployment in a weakened oesophagus carcinoma patient resulting in complications.

Esophageal stents provide palliation and survival time similar to laser and other techniques designed to reduce dysphagia (47). Those who treat malignant oesophageal obstruction are well aware that improvement of dysphagia does not equate with relief of anorexia, nutritional restoration, or prolonged survival. However, stents do allow the patient to enjoy the pleasures of oral alimentation and less time in the physician's office or hospital during the relatively short interval before death.

BENEFITS:

The potential benefits of the ideal oesophageal stent will be easy, rapid, and safe placement, restoration of a predictable and adequate lumen size, optimal palliation of dysphagia and sialorrhea, and provision of the best possible quality of life for the known small quantity of life remaining for the patient with oesophageal cancer.

OESOPHAGEAL STENT IN OESOPHAGO-RESPIRATORY FISTULAS:

A major complication of oesophageal carcinoma is the development of an oesophagorespiratory fistula that, if untreated, typically leads to pulmonary infection and early death. A fistula develops (48,49,51) in approximately 15% of cases and usually should be attributed to the natural history of this disease. Fistulas are the consequence of tissue destruction by carcinoma invading normal tissue. They may first become manifest before any therapy or after irradiation or chemotherapy has produced the desired destruction of the invading cancer. The fistula, however, should not be considered a complication of irradiation, dilation, or other therapy for this malignancy; it is simply a natural event to be expected when necrotic, neoplastic tissue necroses or is removed or displaced.

The most reasonable palliation of the problems of malignant oesophagorespiratory fistulas is stent plastic, silicone, or coated metal expandable (52). Effective occlusion of a fistula within minutes by proper stent placement is satisfying. The elimination of cough, restoration of ability to rest and sleep without the constant cough, and the improvement in quality of life and psychological status of the patient and family provides a positive experience for all concerned.

COMPLICATIONS:

Placement of SEMS is associated with a number of complications (47) both immediate (< 2 wk status post stent) and late (> 2 wk status post stent). Technical complications include failure/problems with stent deployment or expansion, stent misplacement (immediate complication) or migration (late complication), and perforation (both immediate and late). Chest pain is often an immediate symptomatic complication. Stent occlusion (35,38,46) leading to recurrent dysphagia that may be due to tumor ingrowth/overgrowth or food impaction is one of the most common late complications. Bleeding can occur early as well as late following stent placement. Several complications are considered potentially life-threatening are (53) immediate respiratory compromise, aspiration, fistula formation, sepsis, and ultimately, there may be procedure-related death.

FUTURE DEVELOPMENTS:

SEMS represent a rapidly growing therapeutic field. Currently, several new SEMS are under development. Stent with antireflux properties is useful in the gastroesophageal junction. The new stents that devised to have thermal-shaped memory (85) and can rapidly change physical form under different temperature conditions, thus allowing for enhanced removability. Indications for SEMS use are expanding like bronchoesophageal fistula and benign oesophageal strictures. Self expanding plastic stents and biodegradable stents entered the market that extends the indication to benign strictures. Retrievable Metal stents (Song et al) are now in market these also useful for benign strictures. Stent with chemotherapy coating is under trial whether it will alter the course of disease is to be tested by time.

CONCOMITANT PALLIATION

This review of lumen restoration procedures for malignant oesophageal obstruction would be incomplete without emphasizing concomitant measures so essential to care of the "whole patient." Pain relief and nutrition support must be continued throughout the palliative treatment program.

PAIN THERAPY

Pain due to the primary carcinoma and/or regional metastases is a major problem in these diseases. Pain typically becomes serious enough to require regular drug therapy relatively late in the course but may occur in 10% as the first symptom preceding dysphagia (90). It is ordinarily a constant, deep, aching, or boring pain noted in the retrosternal area and may be referred to neck, jaws, or shoulders. This pain responds incompletely to medications like aspirin or acetaminophen plus codeine analogues. In the later stages, morphine sulfate, methadone, or other potent narcotics are required. Liquid morphine or other liquid analgesic preparations are most useful in patients with dysphagia. A sedative at bedtime may help by enhancing the analgesic effect of a narcotic drug. These debilitated patients should be encouraged to use analgesics as needed to be kept comfortable, but they should be observed closely for narcotic side effects. The risk of addiction is low and should not influence the need for adequate pain relief. The extreme fatigue suffered by these patients due to pain and insomnia can be relieved only by an effective pain management regimen.

NUTRITIONAL SUPPORT

The patient's nutritional status should be assessed periodically. Treatment of the protein and calorie malnutrition, so common in these patients should be initiated early. Depending on overall status and prognosis, it may be appropriate to begin this restoration by a percutaneous endoscopic gastrostomy/jejunostomy, by a nasoenteric feeding tube (90) or, rarely, by central venous alimentation. Oral feeding is encouraged as tolerated at the same time, although the tumor-related anorexia and pain

often create major obstacles to achieving adequate nutrition. Early deaths may result as much from the consequences of malnutrition and infection, especially pneumonia, as from spread of the carcinoma.

Other important aspects of supportive care include maintenance of good oral hygiene, adequate dentition, and pulmonary toilet. The care, compassion, and ready availability of a knowledgeable physician who can provide psychological support for the patient and concerned family members are important to the quality of the patient's remaining life.

AIM OF THE STUDY

1. To study the role of Self Expandable Metal Stents for Palliation in Cancer Oesophagus patients.

2. To study the effectiveness of Self Expandable Metal Stents in oesophago-respiratory fistula associated with Cancer Oesophagus.

3. To study the procedural success of placement of Self Expandable Metal Stent in Patients with Carcinoma of the Oesophagus.

4. To study the complications following Self Expandable Metal Stent placement for carcinoma of the oesophagus.

5. To study the effect of placing Self Expandable Metal Stent without Antireflux Valve across the Oesophagogastric Junction.

6. To study the effect of placing Self Expandable Metal Stent in the upper Oesophageal tumours within 2 cm of upper Oesophageal Sphincter.

MATERIALS AND METHODS

STUDY PROTOCOL:

This study was conducted in Department of Digestive Health & Diseases a prestigious department with rich heritage located in the Government Peripheral Hospital, Anna Nagar, Chennai-600 102, attached to Government Kilpauk Medical College, Chennai. The study conducted exclusively in Department of Digestive Health & Diseases inpatients and the patients were subsequently followed as out patients.

The Study period was May 2003 to August 2005. The patients belonged to two groups. First group patients were referred from other hospitals. Department of Digestive Health & Diseases is the referral center to Government Kilpauk Medical College Hospital, Chennai; Government Royapettah Hospital, Royapettah, Chennai; ESI Hospital in Ayanavaram, Chennai; ESI Hospital in KK Nagar, Chennai; Government Peripheral Hospital, Periyar Nagar, Chennai; Government Chest Hospital, Ooteri and many Government Institutions all over the State. Second group of patients presented themselves to Department of Digestive Health & Diseases due to their GI symptoms.

INVESTIGATIONS:

As per our hospital protocol any patient with gastrointestinal symptoms with warning signals such as anemia, loss of appetite, loss of weight, dysphagia, vomiting, blood vomitus, melenic stool and patients more than 40 years even without warning signals are investigated. In any patient with clinical suspicion of carcinoma oesophagus investigation starts from Hemogram (Hemoglobin, Total Count, Differential Count, ESR, Reticulocyte Count, Peripheral Smear, Platelet Count) then Plain Chest X-Ray and Barium Swallow (Fig- 1 to 10) ordered (thick barium, thin barium & mucosal relief films in various views like RAO, LAO, PA, Lateral) which may show any suspicious lesions in the form of filling defect, ulceration, axis deviation, fistulous communication with respiratory tract, contour defect,

luminal dilatation above lesion, gastric fundic air shadow contour abnormalities, aspiration changes (consolidation, air bronchogram & infiltration) and any signs of metastasis into lung or mediastinal nodes.

VIDEO-ENDSOCOPY:

After suspicious Barium swallow study patient posted for Upper GI endoscopy study. Our department is equipped with Videoendoscopy system from Pentax (Model EG-291 P) (Fig- 11, 12) and corresponding processor (Pentax EPK-150 C) (Fig- 13, 14). Our videoendoscopy system (Fig- 15) has an excellent optics. Reporting of endoscopy is done manually in our department. As per our department protocol Videoendoscopy done as inpatient procedure, if the patient was undergoing any therapeutic procedure (Dilatation) the patient was kept under observation if not patient is discharged on the same day. Videoendoscopy usually is done after overnight fasting.

SAME SITTING DILATATION:

If the patient was having obstructive symptoms and videoendoscopy showed growth obstructing the lumen, then after taking biopsy lumen restoration is carried out with wire guided poly vinyl bougie dilation using Savary-Gilliard (SG) dilators (Fig- 16). Dilatation done under two methods one is under fluoroscopic guidance (our department is provided with 1000 MMA machine & a C- Arm) (Fig- 17, 18) in which guide wire in a cannula or 7Fr SG dilator negotiated through the stricture/ narrowing, it is best for initial dilation, tortuous lesions, complex anatomy (Fig- 19, 20 ,21,22); another method is under endoscopic in which Guidewire placed under endoscopic guidance and over that dilatation is proceeded, it was adapted only for subsequent dilatations, straight lesions, without fistula. Routinely after dilatation check Chest X Ray taken unless dilatation is done under fluoroscopic guidance where we can confirm that at the dilatation table itself. If any suspicion of perforation thin contrast study is performed.

NASOGASTRIC TUBE PLACEMENT:

If the patient was having a very tight stricture, high chance of early recurrence of stricture,

dilatation done < 12.8 mm dilators and more importantly in the patient with oesophago-respiratory fistula, naso- gastric tube placed in the same session after dilatation and its position was confirmed by clinical examination. It is important in order to continue feeding in this group of patients.

HISTOPATHOLOGY:

In Videoendoscopy, if any suspicious lesions in the form of large ulcers, nodular growth, proliferative growth, ulceroproliferative growth are found (Fig- 23 to 30), biopsy is taken from the representative lesions. In our department we are using routine biopsy forceps, upto 6 specimens are taken from the growth. The biopsy specimens are mounted in a tissue paper fixed in formalin and sent to our pathology department. After histopathologic report, the correlation with endoscopic finding is between 80-95% of our cases. Biopsy negative is due to insufficient tissue due to gritty lesion, friable tissue or rarely the lesion is due to some benign disease mimicking malignancy. Biopsy is repeated if the suspicion is high.

THE STAGING & ASSESSMENT OF OPERABILITY:

Operability is assessed by helical thin multi slice CT scan (54) of the chest and abdomen (Fig- 31- 34). Inoperable lesions are those in whom tumour is extending outside oesophagus (loss of perioesophageal fat plane) and into neighboring structures like trachea & respiratory tract, aorta, pericardium, pleura, lung and spine (T4); Involvement of nodes- Mediastinal nodes (mid Oesophagus tumours), Cervical Nodes (Upper Oesophagus tumours), perigastric nodes, celiac nodes (Lower Oesophagus & OG Junction tumours); Metastasis into lung, liver & lymphangitis carcinomatosa are picked by CT.

Other than CT even barium swallow findings such as length > 5cm, tortuous lesion, axis deviation, oesophago-respiratory fistula and metastasis in mediastinal nodes or lung secondaries rule out a chance of curative resection. In an ideal setting staging should be done with endoscopic ultrasonogram (54) which picks up T1, T3, T4 stage tumours accurately but its sensitivity for T2 lesion is not accurate. Other investigations used for staging are MRI (54) and PET (Positron Emission Tomography) (54).

OPERABLE TUMOUR:

After staging the tumour, if it was found to be an operable lesion the patient was referred to Surgical oncology department/ Surgical gastroenterology department.

INOPERABLE TUMOUR:

If the lesion appears to be inoperable by CT scan, Surgical Gastroenterologist / Surgical Oncologist opinion is sought to rule out any possibility for curative resection and if branded inoperable patient is taken up for palliative treatment.

WIRE GUIDED DILATATION & FEEDING:

If the patient was having difficulty in swallowing patient was taken for endoscopic luminal restoration procedure. In our department Endoscopic Dilatation is done using the Rule of "3" (Fig- 19 - 22) (three next size dilatation after the dilatation with some resistance). Ideal goal in dilatation is to reach 15 mm dilatation but that could not be achieved in all patients even after weekly dilatation sessions due to the rapid rate of growth of tumour. Complications after dilatation do occur. So it is our policy to put naso-gastric feeding tube of 20-22 G size after dilatation since it may prevent complete closure of the lumen prevents frequent dilatation sessions and related complications and aids in the healing of oesophago-respiratory fistula associated with the tumour and overcomes the anorexia associated with cancer. In inoperable patients after lumen restoration and NG tube placement and proper advice to the patients regarding the feeding formula (high caloric, balanced, mineral and vitamin supplements), frequency of feeding (hrly feeding, nocturnal feeding, consistency of formulas) and complications (tube blockage, Reflux, aspiration, ear pain, glue ear, sore throat) are given.

THE ELIGIBILITY FOR A FREE SEM STENT:

Self Expandable Metal Stents are sponsored by the Government of Tamil Nadu under "Chief Minister's Illness Fund for Cancer Patients". The patients eligible for Self Expandable Metal Stent must be a Resident of Tamil Nadu State and his/ her annual income must not exceed 10,000 Rupees. The patient should produce his/her original Ration Card and attested Xerox copies (proof of address) and an income certificate issued by an Revenue department officer of the rank not below Thasildhar and if necessary an Nativity/ Residence certificate issued by Village Administrative Officer/ Municipal Commissioner depending on the locality.

THE STENT:

The stent used in this study is "CHOO ESOPHAGEAL COVERED STENT"- KOREA (Fig- 35 - 41).

CHOO STENT DESIGN:

Material	: Nitinol (Nickel 55% & Titanium 45%)
Design	: Tubular Wire Mesh Prosthesis with polyurethane membrane constrained in the sheath over a catheter.
Assembly	: 18 Fr (6mm) size & wire guided.
Flexibility	: Highly Flexible Fits to the curvatures
Radial Force	: High Radial Expansile Force
Covering	: Covered with Polyurethane Membrane in the usable Length, both ends are not covered to prevent migration.
Retrievable	: Yes. Nylon Lasso wires present in both ends.
Delivery	: Distal release type.
Stent Length	: 8/ 11 / 14 / 17 cm- Usable length 4 / 7 / 10 / 13
Expanded diameter	: 18 mm
Shortening	: Minimal
Flaring	: 6 mm Proximal and Distal- Anti Migration Property
Delivery System	: Inner Shaft- 70 cm, Outer Sheath- 6mm with a safe lock And a Distal Olive Point

THE PROCEDURE:

After overnight fasting or minimum 6-8 hr fasting patient was taken into the endoscopy theatre. First the procedure was explained to the patient. The written consent from the patient was obtained. Then the patient was put in the left lateral position in the endoscopy table. The naso-gastric tube if present was removed after aspiration. The Self Expandable Metal Stent can be deployed by either ENDOSCOPIC OR FLUOROSCOPIC METHOD:

ENDOSCOPIC METHOD (Fig- 41- 48)**:**

- Video endoscope advanced into the oesophagus till the site of narrowing.
- The proximal margin of growth from the incisors measured and the lumen of the oesophagus assessed.
- Endoscope negotiated through the growth, observing the mucosa in the length of the tumour.
- If any oesophago-respiratory fistula present the site of the fistula from the incisors measured.
- If not possible to negotiate the growth the guide wire placed and Savary- Gilliard dilatation done upto 9 mm at the maximum to 11 mm (32).
- After dilatation endoscope negotiated through growth and distal margin was measured from incisors.
- Endoscope advanced into the stomach, in the stomach retroflexed view of the fundus and cardia to look for any extension of the growth into stomach.
- Stomach further screened to find if there are any synchronous lesions or metastatic lesions or nodal impressions in the stomach and their potential to cause gastric outlet obstruction was assessed.
- Then a 0.035 Zebra Guide wire placed into the duodenum through the endoscope.
- Then the scope removed at the same advancing the guide wire to maintain its position in duodenum.
- During withdrawal of endoscope oesophago-gastric Junction measured and the growth assessed more easily due to the stiffness given by the guide wire inside the scope the distal & proximal

margin of the growth measured, if any oesophago-respiratory fistula present again measured to find the exact position.

- After measuring the length of the lesion Self Expandable Metal Stent's length calculated as follows: 2cm Proximal + Growth Length + 2 cm Distal = Actual length of the stent needed.
- If the length of the tumour is more than available Self Expandable Metal Stent length, Telescoping Stent can be deployed- using two Self Expandable Metal Stents overlap on one another to cover the whole length of the tumour.
- The selected length of Self Expandable Metal Stent is threaded over the Guide wire.
- Endoscope placed at the proximal end of Self Expandable Metal Stent in the oesophagus.
- Under the endoscopic guidance the distal release stent was deployed after removing the lock in the introducer.
- The position of the stent during deployment can be changed easily before full deployment under endoscopic guidance by pulling or pushing the stent introducer.
- After full deployment the stent expansion was assessed by endoscope superficially since only 50%-70% of deployment occurs immediate after deployment and passing the endoscope immediately after stent deployment may increase the chance of stent migration.

FLUOROSCOPIC METHOD (Fig- 49-52)**:**

- Initial Procedure is the same like endoscopic method.
- During withdrawal of endoscope marking the upper end and lower end of the tumour is marked externally with a radio-opaque marker like pin, safety pin.
- The important thing is that the patient's position should not be changed even a bit since it may change the final position of the stent. So the patient should be changed to supine position during marking of the ends of the growth and Self Expandable Metal Stent should be deployed in the same position.
- Instead of external marking, internal marking done by lipiodol injected endoscopically was used for

fluoroscopic guidance. This method overcomes the problems with the external markers.

- Fluoroscopic guidance is better than endoscopic guidance since we can watch the total length of the stent expansion and positioning is relatively easy during deployment.

POST PROCEDURE CARE:

After the procedure patient was instructed to have head end elevation of 45%-60%. Patient may have severe retrosternal pain due to the expanding stent. That should be alleviated by good parental analgesics that can be needed to continue for few days. Immediately after stenting hiccup, vomiting, cough may increase the chance of migration. So, that should be treated with prokinetic agents and antitussives. Patient was kept nil orally for 12- 24 hrs, then plain liquids started followed by liquid food then semi solid diet over a few days.

After 1 day Check X Ray taken (Fig- 53- 56) in Lateral & Right Anterior Oblique views to visualize the stent position and expansion and complications if any like stent migration or under expansion are noted. Liquid contrast study was done in cases of fistula. After 3 days patient was taken up for upper GI endoscopy to assess the stent position. If any changes are to be made can be done by pulling/ pushing the Lasso wire by Rat Tooth Forceps.

INSTRUCTIONS AT DISCHARGE:

At discharge patient was instructed about food habits, to take only semisolid diet, after mashing or thorough chewing and assist the swallowing by frequent intake of plain water in between swallows. To take small feeds but frequent feeds. To avoid lying posture immediately after food and delay going to bed by atleast 2-3 hr after food.

Since the peristalsis is hampered by growth infiltrating into the muscular wall and by Self Expandable Metal Stent holding the wall tightly. Food may impact particularly if taken as food bolus. So the patient should be instructed about the food bolus impaction. Patient should be advised about the complications like food impaction, aspiration, reflux and stent obstruction by tumour ingrowth and overgrowth and stent migration.

For assessing the patient he/she was advised to review at our department out patient clinic once in a fortnight/month.

FOLLOW-UP:

During the follow-up visits patients were asked about their improvement in dysphagia, nutritional improvement (weight gain), quality of life, complications of procedure and disease. Improvement in dysphagia was measured by using dysphagia score. Investigation in the form of Chest X ray and Upper GI endoscopy was done. Quality of life depends not only on the improvement of dysphagia but also the pain control with analgesics and psychological support was also provided.

TREATMENT OF COMPLICATIONS:

If food bolus was found to obstruct the lumen, it was cleared by water jet and mechanical devices like snare, rat tooth forceps. Stent migration can be corrected. Tumour ingrowth/ overgrowth can also be treated at the same sitting.

POST PROCEDURE CHEMO-RADIATION THERAPY:

After Self Expandable Metal Stenting patients were referred for palliative treatment of carcinoma of the oesophagus to Medical Oncology and Radiation oncology departments. Some of the patients are underwent full course of radiotherapy with the Self Expandable Metal Stent in situ.

STUDY OUTLINE

Total number of patients	:	30
Male	:	18
Female	:	12
Male/female ratio	:	1.5 **:** 1
Age group	:	35 **-** 72 years
Mean Age	:	52.5 years
Age range in Males	:	38 **-** 72 years
Mean Age in Males	:	52.5 years
Age range in Females	:	35 **-** 63 years

Mean Age in Males	:	51.7 years
Squamous cell carcinoma	:	28
Adeno carcinoma	:	02
Stent within 2 cm of UES	:	04
Stent extending into stomach	:	07
Tumours with oesophago-respiratory fistula	:	12
Method of stent release		
Endoscopic method	:	21
Fluoroscopic method	:	09
Minor Repositioning	:	02
Immediate expansion	:	30
Immediate complication	:	00
Chest Pain	:	09
Minor Bleed	:	04
Major Bleed	:	00
Choking sensation	:	05
Gastro Oesophageal Reflux	:	11
New Fistula Development	:	00
Late complication	:	04
Minor Stent Blocking	:	03
Tumour In/Over Growth	:	00
Stent Migration	:	01
Radiotherapy after SEMS	:	16
Follow-up	:	15 patients
Maximum follow-up	:	1 yr and 4 months

OBSERVATION

EPIDEMIOLOGICAL FEATURES:

ECONOMIC STATUS:

In my study the patients were selected from general patient pool. Inclusion for palliation with Self Expandable Metal Stent was any patient with biopsy proven inoperable oesophageal carcinoma and the patient must be from lower socio-economic group to be eligible for Self Expandable Metal Stent.

RISK FACTOR

In my study I found that the risk factor in 14 of 18 male patients was smoking, Tobacco chewing in 8 of 12 female patients. Alcohol consumption was found in 10 of 18 male patients and 1 of 12 female patients. Both tobacco use (smoking/oral) & alcohol were in 8 Male patients and 1 female patient.

AGE INCIDENCE & MALE TO FEMALE RATIO (Fig- 57- 59):

Male to Female ratio in my study was 1.5: 1. Age group of patients range from 35- 72 years. Mean age was 52.5 years. Age group of male patients range from 38- 72 years and mean age was 53.5 years. Age group of Female patients range from 35- 63 years and mean age was 51.7 years.

HISTOLOGY OF CARCINOMA OESOPHAGUS (Fig- 60):

In my study Squamous cell carcinoma was the predominant type of carcinoma (28 cases), Adeno carcinoma of Lower end of oesophagus in 2 cases. Adeno carcinoma constituted 6.6% of total cases and Squamous cell carcinoma constituted 93.4% of total cases.

CARCINOMA OESOPHAGUS WITH OESOPHAGO-RESPIRATORY FISTULA (Fig- 61)**:**

In my study 12 cases of carcinoma oesophagus were with oesophago-respiratory fistula. In two patients multiple fistulous openings were made out. The etiology was carcinoma oesophagus in all cases. In the 12 patients 4 had severe lower respiratory infection in the form of pneumonic consolidation with septicemia and poor nutrition, other patients with lesser degree of respiratory infection. Incidence of oesophago-respiratory fistula in this group was 40% somewhat higher than other cases may indicate the advanced disease and pre procedure dilatations may predispose to that. Oesophago-respiratory fistula associated with poor survival. Associated malnutrition has detrimental effect on survival.

METHOD OF STENT DEPLOYMENT (Fig- 62)**:**

The Self Expandable Metal Stent could be deployed by either Fluoroscopic guidance (09) or Endoscopic guidance (21). In our department initially Self Expandable Metal Stent deployed under Fluoroscopic guidance. Later we used the endoscopic guidance and we found that it was equally effective and less time to deploy stents and it avoids radiation exposure to the medical personnel & patient. In this study, 2 patients with Self Expandable Metal Stent deployed under fluoroscopic guidance required minor repositioning of Self Expandable Metal Stent but none of the patients in endoscopic guidance group needed repositioning.

POST PROCEDURE (Fig- 63)**:**

Immediately after Self Expandable Metal Stent placement the expansion of the stent immediate after procedure was good in all cases (100%). Stent expansion checked after 3 days showed good expansion in all cases. There was no shortening of the stent after deployment. Immediate post procedure minor repositioning of stents was done in 2 cases. No immediate post procedure stent migration noted.

Minor Chest pain was present in all cases and severe chest pain in 9 cases (30%). All the

patients improved with analgesics for few days. Only few patients required long term analgesics.

There were no cases of undue major bleed after stent deployment. Stent related minor post procedure bleed in 4 cases, stopped without any intervention.

5 patients had choking sensation after stenting that got relieved by its own in 4 patients, in remaining 1 patient it lasted for few months. 4/5 patients with choking sensation had stent with in 2 cm of upper oesophageal sphincter.

Among the 30 patients, 7 patients had stent positioned into the stomach (2 cases growth extending into stomach and 5 cases lower oesophageal lesion with flange portion of stent extending into stomach). In these 7 patients, 3 had reflux symptoms and in the remaining 23 patients 9 were symptomatic (Fig- 64). Totally 12 patients were symptomatic. Life style modifications (small and frequent feeds, avoid oily foods at night, food to bed gap of 2 hrs, lozenges/ salivary secretogogues) and drugs as prokinetics and Proton pump inhibitors relieved the symptoms.

LATE COMPLICATIONS (Fig- 65)**:**

Late complications occurred in 4 patients. 3 patients had stent blockage and 1 patient had stent migration. In all cases of stent blockage it was because of food material obstructing the lumen. The blocking food material could be easily removed with water jet, Rat Tooth Forceps, Snare and Dipod (usually after fragmenting the food material with any mechanical instrument water jet was used to clear the lumen). After removing the debris oesophagus was screened for any tumour ingrowth/ overgrowth. In none of the patients we observed any tumour In/Over growth large enough to block the lumen.

After 1 month of follow-up, one patient came back with dysphagia because of stent migration. Chest X-Ray and upper GI endoscopy showed that the stent migrated downwards. At the same sitting of upper GI endoscopy stent retrieved with rat tooth forceps by holding the Lasso wire of the stent and pulled back in to the desired portion.

There was no new development of oesophago-respiratory fistula in any of patients in follow-up

after Self Expandable Metal Stent placement.

POST PROCEDURE PALLIATION TREATMENT:

After Self Expandable Metal Stent placement the patients were referred to Medical oncology and Radiation Oncology Departments. Obviously the 12 patients with oesophago-respiratory fistula were deferred for Radiation therapy by the Radiation Oncologist and they were selected for Chemotherapy. Among the 18 patients referred to radiotherapy only 8 patients underwent full radiotherapy (20-30 fractions, 100 rad/fraction). Of the 12 patients referred to chemotherapy, only 4 patents took chemotherapy with 5- fluorouracil as a single agent therapy. 5FU was given as a bolus or an infusion form.

During the course of chemo-radiotherapy we were not able to note any change in the stent related complications like, perforation, new fistulas, bleeding and aortic fistula.

FOLLOW-UP:

All the 30 patients were advised to be on follow-up in our department. Except 15 patients others were lost follow-up at some part of time. 5 patients with oesophago-respiratory fistula and 10 patients without oesophago-respiratory fistula turned up for follow-up. At present 5 patients are in follow-up. 10 patients were admitted with terminal illness in the form of secondaries in lung, bone, liver and brain, severe respiratory infection and septicemia. Maximum follow-up in my study was 1yr and 4 months.

In the fully followed up patients (procedure- Death) and excluding the recently stented patients (15-5=10) average survival after stenting was 6month 29days. When dividing the patients into 2 groups (Fig- 66) by the presence of oesophagorespiratory fistula. In the oesophagorespiratory fistula group average survival was 5 month 5days, in the other group it was 7 month 21 days.

Dysphagia improvement was noted (3 to 1) grade according to O'Sullivan's score in all the patients. Beside the stent related complications the disease related complications like pain due to local extension, infiltration of nerves, vertebral invasion and secondary deposits were taken care by

analgesics and pain clinic (run by Anaesthesia department). 3 of our patients received Nerve blocks, ganglion block including celiac ganglion block for pain control. Psychological support was also provided to our patients. But for the pain, all the patients had improvement in quality of life. After all the great pleasure of taking the food by the natural way was accomplished by this mode of treatment.

DISCUSSION

EPIDEMIOLOGICAL FEATURES:

RISK FACTOR

The geographic variation in oesophageal squamous cell carcinoma strongly hints at the contribution of environmental factors, although the genetic basis for the sporadic form of this cancer has stared to be elucidated. In my study I found that the risk factor in 14 of 18 male patients was smoking, tobacco chewing in 8 of 12 female patients. Alcohol consumption was found in 10 of 18 male patients and 1 of 12 female patients. Both tobacco use (smoking/oral) & alcohol were in 8 Male patients and 1 female patient.

Studies by Burch et al (2), Wynder EL et al (3), Negri E et al (4) show that the tobacco and alcohol act independently as risk factors for Cancer oesophagus. When both alcohol and smoking were present the risk increases synergistically.

SOCIO-ECONOMIC STATUS & SEX INCIDENCE:

In my study the inclusion criteria for palliation with Self Expandable Metal Stent is that the patient must be from lower socio-economic group because the stent was sponsored by the Government for the economically under privileged group. So, that the epidemiological aspects of my study reflect a group of people from lower socio-economic status.

Male to Female ratio in my study was 1.5: 1. Age group of patients ranged from 35- 72 years and mean age was 52.5 years. Age group of male patients ranged from 38- 72 years and mean age was 53.5 years. Age group of female patients ranged from 35- 63 years and mean age was 51.7 years.

In reviewing the works by, Warwick et al (5), Silber et al (6), Day et al (7) cancer oesophagus is common in 6th - 7th decade of life. Carcinoma oesophagus more common in Males than Females (the

ratio is 2-3: 1). The incidence starts to increase after 40 years of age. It is common in black men than other ethnic group in United States probably the socioeconomic status of the black people may have some contribution.

In my study all the patients were from lower socio-economic group. Their mean age at the diagnosis of cancer was 52.5 years 2 decades earlier than the western group. It may be due to the fact that these people were from lower socio-economic group, lack of refrigeration of foods (nitrosamine theory) and increased usage of tobacco and alcohol due to lack of awareness and lack of education.

HISTOLOGY OF CARCINOMA OESOPHAGUS:

In my study Squamous cell carcinoma was the predominant type of carcinoma (28 cases), Adeno carcinoma of Lower end of oesophagus in 2 cases and the ratio between Squamous cell carcinoma and Adeno carcinoma was 1: 0.07. Adeno carcinoma constituted 6.6% of total cases and Squamous cell carcinoma constituted 93.4% of total cases.

According to Greenlee R et al (8), Pera et al (9) overall incidence of oesophageal carcinoma is at an average 2.2- 4.5 per 1,00,000 population. Among these, squamous cell carcinoma is the predominant type - ratio varying from 5-7:1. Now the incidence of adeno carcinoma is increasing in the Western countries. But in my study the adeno carcinoma was less than the existing proportion seen in literature. Adeno carcinoma is related to the acid reflux, Barrett's oesophagus and high body mass index, but these factors were rare in these low socio-economic patients.

CARCINOMA OESOPHAGUS WITH OESOPHAGO-RESPIRATORY FISTULA:

In my study 12 cases of carcinoma oesophagus were with oesophago-respiratory fistula and in two patients multiple fistulous openings were made out. It was because of carcinoma oesophagus in all cases. In the 12 patients, 4 had severe lower respiratory infection, while other patients lesser degree of respiratory infection.

In reviewing literature Gschossmann JM et al (50), Cilley et al (53), incidence of oesophago-respiratory fistula in cancer oesophagus was 5%-15%. In some case series oesophago-respiratory fistula was reported in about 30% of cases of cancer oesophagus. Closure of the fistula with stenting in 66- 100% of cases according to McGrath et al (87) and Ell et al, (52).

In my study the incidence of oesophago-respiratory fistula was 40%. It was somewhat higher than other case series. It may be due to the advanced nature of disease. In all the patients immediately after stenting fistula was well covered (100%) evidenced by contrast studies and clinical improvement.

METHOD OF STENT DEPLOYMENT:

The Self Expandable Metal Stent could be deployed by either Fluoroscopic guidance or Endoscopic guidance. In my study in 9 patients, fluoroscopic method and in 21 patients, endoscopic method was used. In 2 patients Self Expandable Metal Stent deployed under fluoroscopic guidance required minor repositioning of the stent but it was not required in endoscopic guidance group.

According to Singvi et al (40) endoscopic method for stent deployment is well tolerated and technically successful. In reviewing the literature there was no head to head comparison between the techniques of endoscopic and fluoroscopic stent deployment. The advantage of the fluoroscopic method is especially for the stents with fore shortening property. Since we have used the stent without such problem and also endoscopic method was the single sitting procedure after guide wire placement and it also reduces the risk of radiation. So it was our choice to use endoscopic method for deployment.

POST PROCEDURE:

IMMEDIATE EXPANSION:

Immediately after Self Expandable Metal Stent placement the expansion of the stent was complete and it remained so at 3 days later when we screened prior to discharge. There was no shortening of the stent after deployment. Immediate post procedure minor repositioning of stent was

done in 2 cases (Fluoroscopic guided deployment) due to minor problems in fixing the external markers before deployment.

According to Duerig T et al (55), Sandock D et al (56), Ramirez et al (59) Nitinol material is kink resistant, enable the stent have memory properties and fatigue resistant property of gives tensile strength so it ensures the good expansion after deployment.

In my study the immediate expansion was 100%. It was mainly due to mechanical property of the Nitinol stent.

STENT MIGRATION:

No immediate post procedure stent migration was noted in my study. Only minor repositioning of the stent due to improper release of the stent due to patient position change during deployment under Fluoro guidance was seen.

According to Duerig T et al (55), Ell at al (46) Nitinol is adverse to dynamic interference and once deployed, it gently exerts a level of force that prevents recoiling, and this prevents the stent from migrating despite peristaltic activity. Coated stents have more migration than uncoated stents. But the uncovered flanges in the newer coated stents prevent migration.

In my study the there was no migration (0%). It was mainly due to proper deployment of the stent and due to the mechanical property of the Nitinol stent.

MINOR COMPLICATIONS:

CHEST PAIN:

In my study minor chest pain was present in all cases and severe chest pain in 9 cases (30%). The majority of patients improved with analgesics for few days but few patients required long term analgesics. According to Kozarek et al (47), dull chest pain present in 85% of his patients and severe chest pain in 20 % of his patients. It very well correlates with my case series result.

CHOKING SENSATION:

In my study 4/5 patients with choking sensation had stent with in 2 cm of upper oesophageal sphincter. That relieved by its own in 4 patients, in remaining 1 patient it lasted for few months. In Macdonald et al (64) study of 22 cases of stenting near the upper oesophageal sphincter, 93% had technical success, 82% had foreign body like sensation. Study conducted by Profili et al (67) in 9 cases technical success in 8 and in 1 case stent migrated. According to Shim et al (69), Inaba et al (66), Yamamoto et al (71), Goldscmid et al (68), Loizov et al (69), Spinelli et al (70) and Nomori et al (72), it was evident that stenting near the upper oesophageal sphincter is well tolerated particularly after the arrival of the newer age stent, only mild chest pain, choking sensation and globus sensation present in their series. Respiratory compromise due to air way obstruction was noted in 3%- 10% of cases. In some patients with air way compromise tracheobronchial stent along with oesophageal stent solves the problem, but it is technically demanding. In my study the stenting in this area was well tolerated in all these patients but all had only mild symptoms.

MINOR BLEED:

There were no cases with undue major bleed after stent deployment. Only 4 cases of stent related minor post procedure bleed that too stopped without intervention. According to Cwiekel W et al (78), incidence of minor stent related bleed due to the stent expansion into the necrotic tissue in 8- 40% depend on the expansion force of the used stent. In my series 13% of my patients had minor bleed.

REFLUX SYMPTOMS:

Among the 30 stented patients, 7 patients had the stent extended into the stomach. In these 7 patients, 3 had reflux symptoms (3/7=42.8%), and in the remaining 23 patients 9 (9/23=39.1%) were symptomatic. Totally 12 patients were symptomatic. The symptoms got relieved by life style modification, Proton pump inhibitors & prokinetics. There was no significant correlation between the stent position and reflux symptoms.

According to Dua et al (73), Osugi et al (74) and Do et al (75) compared the efficacy of the Self

Expandable Metal Stent with anti reflux valve with stent without such valve for tumours of oesophago-gastric junction and they concluded that Stent with anti reflux valve was more efficacious in preventing the reflux symptoms. According to Laash et al (76), Sabharwal et al (77), Vakil et al (79), Spinelli et al (82) and Siersema et al (80,81,83), the beneficial effect of antireflux valve is doubtful in preventing the reflux symptoms. But these studies were used small number of cases. Latest study conducted by Homs et al (84) (Gastrointestinal Endosc- 2004) done a randomized control trial comparing the Self Expandable Metal Stent with anti reflux valve with stent without such valve for tumours of oesophago-gastric junction and concluded that reflux symptoms equal or more in Stent with anti reflux valve and there is more chance for migration.

In my study the reflux symptoms even though high in both the groups it does not statistically support the concept of more reflux symptoms in stent traversing the OG junction. When comparing the both groups the reflux symptoms the reflux symptoms were higher in the stents placed across the OG junction group (42.8% Versus39.1%) but it was not statistically significant (p= 0.34)

LATE COMPLICATIONS:

In my study late complications occurred in 4 patients stent blockage in 3 patients and stent migration in 1 patient.

STENT BLOCK:

Stent blockage was due to food impaction. The blocking food material can be easily removed with mechanical devices and water jet. After removing the debris oesophagus was screened. None of the patients we observed had any tumour In/Over growth large enough to block the lumen.

Pellicer F et al (57) and Pocek M et al (58) reviewing these author's report I found that stent blocking rate depends on the type of stent (covered or uncovered) and brand of stent (Ultraflex needed more reinterventions for stent blockage). In uncovered stents the tumour ingrowth/ overgrowth (10%-40%) were the most common cause of the stent blockage whereas in covered stents the food

impaction (5-30%) and hyperplastic tissue response (0%-5%) were the common cause.

My study used the covered stent with very good radial expansive force. So naturally the stent block was 10% and it was due to food impaction.

STENT MIGRATION:

Stent migration was noted in 1 case. After 1 month of follow-up that patient came with dysphagia, the stent had migrated downwards. Upper GI endoscopy was done and at the same sitting stent was retrieved by holding the Lasso wire and repositioned.

According to Ramirez FC et al (59), Winkelbauer FW et al (60), stent migration depend on the type of stent (covered or uncovered). In uncovered stents, the stent extend into the submucosa and the tumour ingrowth prevents the stent migration, so it was low in incidence (3%-8%). Whereas in covered stent the stent migration occurred more commonly, particularly with fully covered type (5-30%).

In my study the stent migration rate was 3.3%, lower than the published results. It was due to the stent design, large uncovered flanges prevent stent migration and it may be due to the insufficient follow-up that may under estimate the stent migration rate.

POST PROCEDURE PALLIATION TREATMENT:

After Self Expandable Metal Stent placement the patients were referred to Medical oncology and Radiation Oncology Departments. Among the 18 patients referred to radiotherapy only 8 patients underwent radiotherapy. In the patients who had undergone radiotherapy, it was given as 20-30 fractions (100 rads/ fraction). 12 patients were referred to chemotherapy, but only 4 patents underwent chemotherapy with 5- fluorouracil as a single agent therapy.

Among these patients 5 patients with oesophago-respiratory fistula and 10 patients without oesophago-respiratory fistula were under follow-up. At present 5 patients in follow-up. The remaining 10 patients were lost due to terminal illness. In the remaining 15 patients we lost follow-up at some part of time.

During the course of chemo-radiotherapy we were not able to observe any new complications like, perforation, new fistulas, bleeding and aortic fistula.

According to Nguyen et al (61), Maier et al (88), Raijman et al (89) the use of expandable metal stents during the chemoradiation therapy, complications like perforation or new fistula or bleed are no more common than in any patient without chemo-radiation therapy. But Nishikawa, Tajiri et al (63) says that after chemoradiation therapy perforation was 31%, air way compromise in 23% and bleeding in 15%.

In my study there were no complications following chemoradiation therapy. Because in the followed patients only 12 patients had underwent post stent treatment either Chemotherapy or radiotherapy but not the both. The amount of radiotherapy given at our place was also lesser than the amount of radiotherapy given in sited reference. Our patients were also poorly compliant after stenting since they were able to eat through the mouth and did not bother about the chemoradiotherapy. These were the explanations for the lower incidence of complications in my study.

FOLLOW-UP:

IMPROVEMENT IN DYSPHAGIA:

All the 30 patients immediately after stenting dysphagia improvement was (3 to 1) grade according to O'Sullivan's score. Even after few months of follow-up excluding the patients lost follow-up in the remaining patients dysphagia improvement persisted.

According to Frimberger et al (85), Domschke et al (86), dysphagia score were improved from 3.3 to 1.2 in their series with various Self Expandable Metal Stents. In my study also I have observed that there was a good response in the dysphagia score.

POST PROCEDURE SURVIVAL:

In my study average survival after stenting (in the fully followed up patients from procedure-death and excluding the recently stented patients) was 6 month 29 days. When dividing the patients

into 2 groups by the presence of oesophagorespiratory fistula. In the oesophagorespiratory fistula group average survival was 5 month 5days, in the other group it was 7 month 21 days. The survival in the oesophagorespiratory fistula negative group was relatively better than oesophagorespiratory fistula positive group.

According to Warwick et al (5), Shields SJ et al (36) survival in the cancer oesophagus after palliation with endoprosthesis vary from 4 months- 11 months. In my study the survival is comparable when excluding the patients lost their follow up. The poor survival rate in oesophagorespiratory fistula group may be due to the advanced nature of the disease even before stenting. Because of small number of patients the study can not effectively address this issue.

PAIN CONTROL & QUALITY OF LIFE:

Pain due to local extension, infiltration of nerves, vertebral invasion and secondary deposits was the major problem taken care by analgesics and pain clinic. Psychological support was also provided to our patients. Quality of life in all these patients improved.

According to Bethge N et al (62), Knyrim K et al (44), a significant improvement in Karnofsky performance score and HRQOL (Health Related Quality Of Life) after Self Expandable Metal Stenting in cancer oesophagus. Even though I have not used any performance score in my study, in general the patient's quality of life improved due to relief of dysphagia and other supportive measures like pain relief and psychological support.

CONCLUSION

1. Self Expandable Metal Stents for Palliation in Carcinoma Oesophagus gives excellent relief of dysphagia and provides good quality of life to these patients. There is improvement in general well being by allowing the patient to eat and offers better aesthetic appeal.

2. Self Expandable Metal Stents in oesophago-respiratory fistula completely covers the fistula immediately after the procedure. It improves the general condition, controls respiratory infection, improves the nutritional state and offers good quality of life in these patients with Carcinoma Oesophagus.

3. Procedural success of deploying Self Expandable Metal Stent in patients with Carcinoma of Oesophagus is good. It is very convenient and easy to deploy the stent and is less cumbersome too. Excellent expansion of the stent occurs immediately after deploying and relieves the dysphagia in the immediate post procedure period.

4. Complications following proper placement of Self Expandable Metal Stents for carcinoma oesophagus are minimal but they are well managed. No major immediate post stenting complications occurred in my study. Expected number of late complications in the form of stent blockage and stent migration occurred but they were managed well.

5. There is no increase in the incidence of reflux symptoms in the group where stents without any anti reflux mechanism are placed across the Oesophagogastric Junction.

6. There are only minor complications in the form of choking sensation when the Self Expandable

Metal Stent properly placed in the upper Oesophageal Lesion within 2 cm of upper Oesophageal Sphincter.

BIBILIOGRAPHY

1. Malkan G, Mohandas KM, Epidemiology of digestive cancers in India. 1. General principles and esophageal cancer. Indian J Gastroenterology. 1997;16:98-102.
2. Burch PRJ et al- oesophageal cancer in relation to cigarette and alcohol consumption, J Churon Inst 1984;37:793.
3. Wynder EL, Mabuchi K et al. Etiological and environmental factors in cancer oesophagus- JAMA, 1973;266:1546.
4. Negri E, La Veechia C, Franceschi S et al - Attributable risks for oesophageal cancer in northern Italy- Eur J cancer, 1992;28A:1167.
5. Warwick GP et al. Some aspects of epidemiology and aetiology of the oesophageal cancer, Adv Cancer Res, 1973;17:81.
6. Silber W et al - Carcinoma of oesophagus: Aspects of epidemiology and aetiology, Proc Nutr Soc 1985;44:101.
7. Day NE, Munoz N et al. Cancer epidemiology and prevention, Philadelphia, WB Saunders, 1982:596.
8. Greenlee R, Murray T, Bolden S et al- Cancer statistics, 2000, carcinoma cancer J clin 50(1):7-33-2000.
9. Pera M, Cameron AJ, Trastek VF et al. Increasing incidence of adeno carcinoma of the oesophagus and oesophago-gastric junction. Gastroenterology 1993;104:510-513.
10. Swaroop VS, Deasi DC, Mohandas KM, Dhir V, Deshpande RK, Desai PB. Dilatation of esophageal strictures induced by radiation injury for cancer of the esophagus. Gastrointest Endosc. 1994;40:311-315.
11. Moses FM, Peura DA, Wong RKH et al. Palliative dilation of esophageal carcinoma. Gastrointest. Endosc. 1985; 31: 613.

12. Mohandas KM, Shanthi Swaroop V, Desai DC. Marked wire guided esophageal dilatation and the need for fluoroscopy. Gastrointest Endosc. 1992;38:634-635.
13. Heit HA, Johnson LF, Siegel SR, et al. Palliative dilation for dysphagia in esophageal carcinoma. Ann Intern Med. 1978;89:629-631.
14. Cassidy DE, Nord HJ, Boyce HW. Management of malignant esophageal strictures: role of esophageal dilation and peroral prosthesis. Gastroenterology 75:173.
15. Ahmed ME, Gustavsson S. Current palliative modalities for esophagal carcinoma. Acta Chir. Scand. 1990; 156: 958.
16. Kubba AK, Krasmer N. An update in the palliative management of malignant dysphagia. Eur. J. Surg. Oncol. 2001; 26: 11629.
17. Boyce HW Jr. Palliation of advanced esophageal cancer. Semin Oncol.;11:186-195.
18. Dallal HJ, Smith GD, Grieve DC et al. A randomized trial of thermal ablative therapy versus expandable metal stents in the palliative treatment of patients with esophageal carcinoma. Gastrointest. Endosc. 2001; 54: 549-57.
19. Fleischer D, Kessler F, Haye O. Endoscopic Nd:YAG laser therapy for carcinoma of the esophagus: a new palliative approach. Am J Surg. ;143:280-283.
20. Ell C, Riemann JF, Lux G, et al. Palliative laser treatment of malignant stenoses in the upper gastrointestinal tract. Endoscopy. 1986(suppl):21-26.
21. Loizou LA, Grigg D, Atkinson M, et al. A prospective comparison of laser therapy and intubation in endoscopic palliation for malignant dysphagia. Gastroenterology. 1991;100:1303-1310.
22. Cottier DJ, Carter CR, Smith JS, et al. The combination of laser recanalization and endoluminal intubation in the palliation of malignant dysphagia. J R Coll Surg Edinb. 1997;2:19-20.
23. Adam A, Ellul J, Watkinson AF, et al. Palliation of inoperable esophageal carcinoma: a prospective randomized trial of laser therapy and stent placement. Radiology. 1997;202:344-348.
24. Savage AP, Baigrie RJ, Cobb RA, et al. Palliation of malignant dysphagia by laser therapy. Dis

Esophagus. 1997;10:243-246.

25. Harbord M, Dawes RF, Barr H et al. Palliation of patients with dysphagia due to advanced esophageal cancer by endoscopic injection of cisplatin/epinephrine injectable gel. Gastrointest. Endosc. 2002; 56: 644-51.
26. Lightdale CJ, Heier SK, Marcon NE, et al. Photodynamic therapy with porfimer sodium versus thermal ablation therapy with Nd:YAG laser for palliation of esophageal cancer: a multicenter randomized trial. Gastrointest Endosc. ;42:507-512.
27. Payne-James JJ, Spiller RC, Misiewicz JJ, et al. Use of ethanol-induced tumor necrosis to palliate dysphagia in patients with esophagogastric cancer. Gastrointest Endosc. 1990;36:43-46.
28. Overholt BF. Photodynamic therapy and thermal treatment of esophageal cancer. Gastrointest Endosc Clin North Am. 1992;2:433-455.
29. Scheider DM, Siemens M, Cirocco M, et al. Photodynamic therapy for the treatment of tumor ingrowth in expandable esophageal stents. Endoscopy. ;29:271-274.
30. Marcon NE. Photodynamic therapy and cancer of the esophagus. Semin Oncol. 1994;21(6 suppl 15):20-23.
31. Conio M, Gostout CJ. Photodynamic therapy for the treatment of tumor ingrowth in expandable esophageal stents. Gastrointest Endosc. 1998;48:225.
32. Raijman I, Siddique I, Ajani J et al. How much dilatation is necessary prior to placement of an esophageal stent? Gastrointest Endosc. 1997;45:213.
33. O'Connor T, Watson R, Lepley D, et al. Esophageal prosthesis for palliative intubation. Arch Surg. 1963;87:275-279.
34. Earlam R, Cunha-Melo JR. Malignant oesophageal strictures: a review of techniques for palliative intubation. Br J Surg. 1982;69:61-68.
35. O'Connor T, Watson R, Lepley D, et al. Esophageal prosthesis for palliative intubation. Arch Surg. 1963;87:275-279.

36. Shields SJ. Esophageal self-expandable metallic stents. Gastrointest Endosc. 1997;45:439-442.
37. Cotton PB. Metallic mesh stents: is the expanse worth the expense? Endoscopy. 1992;24:421-423.
38. Fleischer DE. Stents, cloggology, and esophageal cancer. Gastrointest Endosc. 1996;43:258-260.
39. Atkinson M, Ferguson R. Fiberoptic endoscopic palliative intubation of inoperable oesophagogastric neoplasms. Br Med J. 1977;1:266-267.
40. Singhvi R, Abbasakoor F, Manson JM. Insertion of self-expanding metal stents for malignant dysphagia: assessment of a simple endoscopic method. Ann. R. Coll. Surg. Engl. 2000; 82: 2438.
41. Mosca F, Consoli A, Persi A, portale TR. Comparative retrospective study on the use of plastic and Self Expandable Metal Stents in the palliative treatment of malignant strictures of the esophagus and cardia. Dis Esophagus. 2003;16:119-125.
42. Angueria CE, Kadakia SC. Esophageal stents for inoperable esophageal cancer- which to use? Am J Gastroenterol 1997;92:373-760
43. DePalma GD, DiMatteo, Romano G et al. Plastic prosthesis versus expandable stents for palliation of inoperable esophageal thoracic carcinoma- a controlled prospective study. Gastrointest Endosc 1996;43:478-82.
44. Knyrim K, Hans-Joachim W, Bethge N et al. A controlled trial of an expandable metal stent for palliation of esophageal obstruction due to inoperable cancer. N Engl J Med 1993;339:1302-07.
45. Vermeijden J, Bartelsman J, Fockens P et al. Self expanding metal stents for palliation of esophagocardial malignancies. Gastrointest Endosc 1995;41:58-63.
46. Ell C, Hochberger J, May A et al. Coated and uncoated Self Expandable Metal Stents for malignant stenosis in the upper GI tract preliminary clinical experience with Wallstents. Am J Gastroenterol 1994;89:1496-1500.
47. Kozarek R, Ball T, Patterson D. Metallic Self expanding stent application in the upper GI tract-Caveats and concerns. Gastrointest Endosc 1994;38:1-6.
48. Raijman I, Siddique I, Ajani J et al. Palliation of malignant dysphagia and fistula with the

Wallstent- experience with 101 patients. Gastrointest Endosc 1997;45:215A.

49. Little AG, Ferguson MK, DeMeester TR et al. Esophageal carcinoma with respiratory fistula. Cancer 1984;53:1322-28
50. Gschossmann JM et al- Malignant oesophago-respiratory fistula in patients with oesophageal cancer: Cancer 1993; 24: 127-32.
51. Macken E, Gevers A, Hiele M, et al. Treatment of esophagorespiratory fistulas with a polyurethane-covered self-expanding metallic mesh stent. Gastrointest Endosc. 1996;4:324-326.
52. May A, Ell C. Palliative treatment of malignant esophagorespiratory fistulas with Gianturco-Z stents: a prospective clinical trial and review of the literature on covered metal stents. Am J Gastroenterol. 1998;93:532-535.
53. Cilley et al- Cause of death in carcinoma oesophagus- Am J Gastroenterol- 1989; 25:527-37.
54. Rankin S, Mason R. Staging of esophageal carcinoma. Clin. Radiol. 1992; 46: 3737.
55. Duerig T et al- Super elastic Nitinol for medical devices- medical plastics and biomaterials, 1997
56. Sandock D et al- Tubular medical prosthesis for use in a body lumen- United States Patent 5,800, 519
57. Pellicer F et al- Self Expandable Oesophageal Metal Stents in the palliative treatment of oesophageal cancer. Rev. Esp. Enferm Dig, 1996: 34-57
58. Pocek M et al- Palliative treatment of neoplastic strictures by Self Expandable Nitinol Stent, Eur Radiol 1996; 34: 453-462.
59. Ramirez FC et al- Esophageal Self Expandable Metal Stents - indications, practice, techniques and complications; Results of a national survey- Gastrointest endosc- 1997; 39: 243-53.
60. Winkelbauer FW et al- Palliative treatment of obstructing esophageal cancer with nitinol stents: value, safety, and long term results. AJR Am J Roentgenol- 1996; 23: 234-41.
61. Nguyen et al- The use of expandable metal stents during the chemoradiation therapy- Gastroenterol. 1998; 114.

62. Bethge N et al- A prospective trial of Self Expandable Metal Stents in the palliation of malignant esophageal obstruction after failure of primary curative therapy. Gastrointest Endosc- 1994.
63. Nishikawa Y, Tajiri IH, Endo H et al. Significance and problems of Self Expandable Metal Stents for esophageal cancer after chemoradiotherapy. Gastrointest Endosc. 2001; 53: AB156.
64. Macdonald et al, Edwards RD, Moss JG. Patient tolerance of cervical esophageal metallic stents. J Vasc Interv Radiol. 2000;11:891-898.
65. Shim CS, Jung IS, Bhandari S, Ryu CB, Hong SJ, KIM JO, Cho JY, Lee JS, Kim Boston Scientific. Management of malignant strictures of cervical esophagus with a newly designed self expanding metal stent. Endoscopy;2004;36:554-557.
66. Inaba Y, Kamata M, Aramaki T, Takaki H. Cervical esophagus stent placement via a retrograde Transgastric route. Br J Radiol. 2004;77:787-789.
67. Profili S, Meloni GB, Feo CF, Ginesu GC. Self Expandable Metal Stent in the management of cervical esophagus and hypopharyngeal strictures. Clin Radiol.2002;57:1028-1033.
68. Goldschmid S, Boyce HW Jr, Nord HJ, et al. Treatment of pharyngoesophageal stenosis by polyvinyl prosthesis in. Am J Gastroenterol. 1988;83:513-518.
69. Loizou LA, Rampton D, Bown SG. Treatment of malignant strictures of the cervical esophagus by endoscopic intubation using modified endoprostheses. Gastrointest Endosc. 1992;38:158-164.
70. Spinelli P, Cerrai FG, Meroni E. Pharyngo-esophageal prostheses in malignancies of the cervical esophagus. Endoscopy. 1991;23:213-214.
71. Yamamoto R, Tada H, Kishi A, Tojo T. Double stent for combined esophago-airway lesion. Jpn J Thorac Cardiovasc Surg. 2002;50:1-5.
72. Nomori H, Horio H, Imazu Y, Sumasu K. Double stenting for esophageal and tracheobronchial stenoses. Ann Thorac Surg. 2000;70:1803-1807.
73. Dua KS, Kozarek R, Kim J, Evans J, lang I, Hogan WJ. MCW Self Expandable Metal esophageal Stent with anti-reflux mechanism. Gastrointest Endosc. 2001;53:603-613.

74. Do YS, Choo SW, Suh SW, Kang WK, Rhee PL et al. Malignant esophagogastric junction obstruction: Palliative treatment with an anti reflux valve stent. J Vasc Interv Radiol. 2001;12:647-651.

75. Osugi H, Lee S, Tokuhara T, Kaseno S, Takada N et al. Usefulness of SEM with antireflux mechanism as a palliation for malignant strictures at the gastroesophageal junction. Surg Endsosc. 2002t;16:1478-1479.

76. Laasch HU, Marriott A, Wilbraham L et al. Effectiveness of open versus antireflux stents for palliation of distal esophageal carcinoma and prevention of symptomatic gastroesophageal reflux. Radiology 2002; 225: 35965.

77. Sabharwal T, Hamady MS, Chui S et al. A randomised prospective comparison of the flamingo Wallstent and Ultraflex stent for palliation of dysphagia associated with lower third esophageal carcinoma. Gut 2003; 52: 9226.

78. Rozanes I, Poyanli A, Acunas B. Palliative treatment of inoperable malignant esophageal strictures with metal stents: one center's experience with four different stents. Eur. J. Radiol. 2002; 43: 196203.

79. Vakil N, Morris AI, Marcon N et al. A prospective, randomized, controlled trial of covered expandable metal stents in the palliation of malignant esophageal obstruction at the gastroesophageal junction. Am. J. Gastroenterol. 2001; 96: 17916.

80. Siersema PD, Hop WCJ, van Blankstein M et al. A comparison of three types of covered metal stents for the palliation of patients with dysphagia caused by esophagogastric carcinoma: a prospective, randomized study. Gastrointest. Endosc. 2001; 54: 14553.

81. Siersema PD, Marcon N, Vakil N. Metal stents for tumors of the distal esophagus and the gastric cardia. Endoscopy 2003; 35: 7985.

82. Spinelli P, Cerrai FG, Ciuffi M, et al. Endoscopic stent placement for cancer of the lower

esophagus and gastric cardia. Gastrointest Endosc. ;40:455-457.

83. Siersema PD, Hop WC, Dees J, et al. Coated self-expanding metal stents versus latex prostheses for esophagogastric cancer with special reference to prior radiation and chemotherapy: a controlled, prospective study. Gastrointest Endosc. 1998;47:113-120.
84. Homs MY, Wahab PJ, Kuipers EJ, Grool TA, Siersema PD et al. Esophageal stents with antireflux valve for tumours of distal esophagus and gastric cardia/; a randomized trial. Gastrointest Endosc. 2004;60:695-702.
85. Frimberger E, Expanding spiral: a new type of prosthesis for the palliative treatment of malignant esophageal stenosis. Endoscopy. 1983; 15: 213-214.
86. Domschke W, Forster EC, Matek W et al. Self Expandable Mesh Stent for the esophageal cancer stenosis. Endoscopy. 1990; 22: 134-136.
87. Mc Grath JP, Browne M, Riordan C et al. Expandable metal stents in the palliation of malignant dysphagia and esophageal-respiratory fistulae. Ir. Med. J. 2001; 94: 2702.
88. Maier A, Anegg U, Lunzer R et al. The effect of external beam irradiation after endoscopic palliation of esophageal carcinoma. Oncol. Rep. 2000; 7: 3759.
89. Raijman I, Siddique I, Lynch P. Does chemoradiation therapy increase the incidence of complications with self-expanding coated stents in the management of malignant esophageal strictures? Am J Gastroenterol. ;92:2192-2196.
90. Loizou LA, Rampton D, Atkinson M, et al. A prospective assessment of quality of life after endoscopic intubation and laser therapy for malignant dysphagia. Cancer. 1992;70:386-391.

PROFORMA

PALLIATION OF CARCINOMA OESOPHAGUS WITH SELF EXPANDABLE METAL STENT

NAME: AGE: SEX:

ADDRESS:

DDHD NO:

IP NO:

COMPLIANTS:

CO-MORBID ILLNESS:

HB:

TC:

DC:

ESR:

BLOOD SUGAR- RANDOM:

BLOOD UREA:

SR. CREATININE:

ECG:

CHEST X RAY:

BARIUM SWALLOW:

OGD:

LENGTH OF LESION:

MORPHOLOGY OF LESION:

OESOPHAGO RESPIRATORY FISTULA:

EXTENSION INTO STOMACH:

NUMBER OF BIOPSIES TAKEN:

DILATATION: BALLOON/ BOUGIE

NASOGASTRIC TUBE PLACEMENT:

CT CHEST:

THERAPY:

PREPROCEDURE DILATATION:

BRAND OF THE STENT:

LENGTH OF THE STENT:

BATCH OF THE STENT:

DATE OF STENT DEPLOYMENT:

METHOD OF DEPLOYMENT:

ENDOSCOPIC / FLUOROSCOPIC

POST PROCEDURE:

CHECK X RAY:

CONTRAST X RAY (OESOPHAGO RESPIRATORY FISTULA):

PATIENT:

CHEST PAIN:

CHOKING SENSATION:

BLEEDING:

HEART BURN:

STENT:

IMMEDIATE EXPANSION:

MIGRATION:

REPOSITIONING:

LATE COMPLICATION:

STENT BLOCKING:

STENT MIGRATION:

POST STENT PALLIATIVE THERAPY:

CHEMOTHERAPY:

RADIOTHERAPY:

FOLLOW-UP

PATIENT SYMPTOMS:

WEIGHT GAIN:

PAIN STATUS:

NUMBER OF HOSPITAL ADMISSION: